

**REMARKS**

Applicants have amended claim 24. Support for this amendment can be found throughout the specification as filed. For example, support may be found in the specification at page 25, line 24 through page 26, line 7; and at page 64, lines 22-27. No new matter has been added by way of amendment. Claims 24-33 will be pending upon entry of this amendment.

**The Rejection of Claims 24-33 under 35 USC §112, First Paragraph,  
(New Matter), Should Be Withdrawn**

The Examiner rejected claims 24-33 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner argued that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Specifically, the Examiner argued that,

“Applicant’s amendment does not point out the support for the newly added limitations, and the specification as-filed or original claims do not appear to provide adequate written description of the following limitations in claim 24: ‘wherein the polypeptide has a B7-like co-stimulatory activity selected from the group consisting of: ability to modulate T-cell proliferation, ability to modulate cytokine production, ability to up-regulate molecules that mediate cell-cell interaction, and ability to modulate antibody secretion by B-cells.’”

The Examiner stated, “Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for these limitations.”

Applicants traverse the rejection. Applicants submit that support for the limitations of claim 24 cited above can be found throughout the specification as filed. For example, written support can be found at page 25, line 24 through page 26, line 7; and at page 64, lines 22-27 of the instant specification.

In particular, page 25, line 24 through page 26, line 7 states (with similar teachings on page 64), “a B7-like activity includes the ability to modulate...cell proliferation...and/or function, particularly that of immune cells...Examples of modulation of immune cell function...include T-cell proliferation, modulation of cytokine production... (such as IL-2, IL-4, IL-5, IL-10, interferon-gamma, tumor necrosis factor alpha...)...and modulation of antibody secretion by B-cells.”

In addition, Applicants have amended claim 24 as described in detail below, further limiting recitation of “modulate” to “up-regulate”; to delete the limitation reciting modulation of “molecules” that

mediate cell-cell interaction; and to list the “cytokines” up-regulated in the limitation alternative of claim 24 where they appear.

Therefore, Applicants submit that the limitations in claim 24 are not new matter, but are supported by the instant specification as outlined above. Accordingly, the limitations of claim 24 were clearly disclosed in the specification and claims as filed, and do not introduce new concepts, but are fully compliant with the requirements of the first paragraph of 35 U.S.C. §112. Applicants request reconsideration and withdrawal of the rejection of claims 24-33 under 35 U.S.C. §112, first paragraph (New Matter).

**The Rejection of Claims 24-33 under 35 USC §112, First Paragraph,  
(Written Description), Should Be Withdrawn**

The Examiner further rejected claims 24-33 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner argued that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner stated that:

“A. Applicant is not in possession of a method employing a polypeptide which has the activity to ‘modulate’ T cell proliferation, cytokine production, or antibody secretion.

The recitation of the activity to ‘modulate’ the recited T cell functions encompasses two mutually exclusive activities, specifically, to upregulate and to downregulate the recited functions. Since a single polypeptide cannot simultaneously possess these two mutually exclusive activities, Applicant is not in possession of such polypeptide, and therefore, the claimed methods.

B. Applicant is not in possession of a method employing a polypeptide which has the activity to modulate a generically recited ‘cytokine’ production, or to up-regulate generically recited ‘molecules’ that mediate cell-cell interaction.

One of skill in the art at the time the invention was made was aware of a large number of structurally and functionally diverse cytokines and molecules that mediate cell-cell interaction; one of skill in the art was also aware that only a subset of these cytokines and molecules may be modulated and/or up-regulated by the recited polypeptide.

Applicant has not provided sufficient structural and functional characteristics of the genera of ‘cytokines’ and ‘molecules’ encompassed by the instant claim language...”

Applicants respectfully traverse the rejection for the following reasons:

First, Applicants have amended claim 24 to change "modulate" to "up-regulate" wherever it appears. Support for this amendment can be found in the specification, for example at page 25, lines 6-7. In addition, in an effort to expedite prosecution and in no way acquiescing to the Examiners' rejection, Applicants have amended claim 24 to delete reference to up-regulation of "molecules" that mediate cell-cell interaction. Furthermore, Applicants have amended claim 24 to recite the "cytokines" by name, specifically, "a cytokine selected from the group consisting of IL-2, IL-4, IL-5, IL-10, IFN $\gamma$ , and TNF $\alpha$ ". Applicants note that support for these limitations may be found for example at page 25, lines 6-7; at page 25, line 24 through page 26, line 7; and at page 64, lines 22-27. Therefore, the limitations of claim 24 as presently amended are fully described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. §112, first paragraph (Written Description) rejection of claims 24-33.

### CONCLUSION

In view of the amendments and remarks herein, Applicants believe that the objections and rejections presented by the Examiner are now overcome and that this application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

This paper is being filed timely, as a request for a three month extension of time is being filed concurrently herewith. It is believed no other fees are required. In the event any additional fees are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

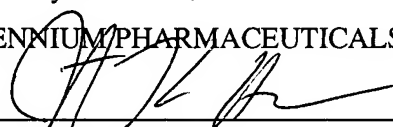
Entry of the remarks made herein is respectfully requested.

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Respectfully submitted,

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